

From: Ruth Schenk
To: Daniel Cullen
Cc: Carl Ryan; Cleophas Jackson; Khesha Reed; Smith.Jay@epamail.epa.gov
Subject: Re: Fw: External Visits to Manufacturers/Labs (SEAs, Verification, Witness Testing)
Date: 03/16/2010 10:22 AM
Attachments: GM HD Cert and lab audit.doc
GM - follow up HD cert and lab audit 20100310 1528.doc
GM - announcement HD cert and lab audit 20100310 1708.doc

Dan,

Thank you for forwarding the project files describing the HD Engine Manufacturer's Site Confirmatory Testing. I've reviewed the process flow, letters, checklists, training, and approach.

I have a comment to add regarding the fuel and DEF analysis. To ensure the chain of custody of the fuel and DEF samples, place a tamper proof tape on the bottles, assign a unique number to the sample (i.e. GM Cert Fuel Sample #01, 3/15/2010, init), date and initial the tape (a rep from GM and a rep from EPA), have the staff performing the analysis note the condition of the tape and bottle before starting analysis. Develop a receipt that you keep the original and give a copy to GM that has the unique number on it, date, who has control of the sample/took the sample from GM and will deliver it to NVFEL, and you can include a place for the test results or a notation that the test results will be stapled to the receipt when received. Then you can keep the receipt and results with the report file.

Thank you,
Ruth

▼ Daniel Cullen---03/15/2010 11:00:26 AM---Ruth: The following document addresses your concerns:

From: Daniel Cullen/AA/USEPA/US
To: Ruth Schenk/AA/USEPA/US@EPA
Cc: Cleophas Jackson/AA/USEPA/US@EPA, Smith.Jay@epamail.epa.gov, Khesha Reed/DC/USEPA/US@EPA, Carl Ryan/AA/USEPA/US@EPA
Date: 03/15/2010 11:00 AM
Subject: Fw: External Visits to Manufacturers/Labs (SEAs, Verification, Witness Testing)

Ruth:

The following document addresses your concerns:



GM HD Cert and lab audit.doc

The files for Appendices B & C are attached here. They are left in change tracking mode so you can see the comments (and this is how they are pasted in the above file). If you would like to review them in "presentation mode" I have attached them here, simply pick "Final" from the drop-down review box.



GM - follow up HD cert and lab audit 20100310 1528.doc



GM - announcement HD cert and lab audit 20100310 1708.doc

I will talk to you Tuesday,

Dan

----- Forwarded by Daniel Cullen/AA/USEPA/US on 03/15/2010 10:40 AM -----

From: Cleophas Jackson/AA/USEPA/US
To: Daniel Cullen/AA/USEPA/US@EPA
Date: 03/11/2010 04:50 PM
Subject: Fw: External Visits to Manufacturers/Labs (SEAs, Verification, Witness Testing)

fyi

Cleophas Jackson
U.S. EPA - OTAQ
Assistant Division Director
Compliance and Innovative Strategies Division
2000 Traverwood Drive
Ann Arbor, MI 48105
(734) 214-4824
(734) 214-4051 FAX

----- Forwarded by Cleophas Jackson/AA/USEPA/US on 03/11/2010 04:50 PM -----

From: Ruth Schenk/AA/USEPA/US
To: Cleophas Jackson/AA/USEPA/US@EPA, Khesha Reed/DC/USEPA/US@EPA
Cc: Maria Peralta/AA/USEPA/US@EPA
Date: 03/11/2010 03:54 PM
Subject: External Visits to Manufacturers/Labs (SEAs, Verification, Witness Testing)

Cle
Khesha

I am hearing that SEA, witness testing and verification programs are probable activities for the HD Engine Team. I am including Maria Peralta on this note as I have discussed the quality assurance concerns with Maria.

This note is to re-iterate the quality assurance/oversight questions that were brought up in February 2009 when SEAs were initially discussed. The purpose of the questions is to ensure that external programs (e.g. SEAs, witness testing and verification programs) are thoroughly developed, based on objective requirements, consistently applied, and conducted by staff conversant with their roles and responsibilities. From my soapbox -- this may be the only time that many of the manufacturer's staff come into contact with EPA personnel and it is imperative that

the Agency is perceived as a professional organization.

Prior to any external visits that are used to evaluate or audit manufacturers or their laboratories, Quality Assurance is requesting a review of the process to ensure that the upfront work has been completed and that the programs are poised for success. This is the same approach and review that was used for the In-Use Verification Program.

Quality assurance/oversight questions:

- Planning
 - What is the objective of the external visit?
 - Who is on the team?
 - Who is the team leader?
 - What are the roles and responsibilities for the participants?
 - Are team members trained?
 - Are credentials necessary?
 - What is being reviewed? Have detailed checklists of what is to be reviewed when you arrive. This will ensure consistency between visits, consistency between teams, and ensure that all necessary items are reviewed. Checklists will also remove subjective evaluations. This does not mean that staff cannot make observations; however, if there isn't a written requirement (CFR, manufacturer letter, etc) then the audit team cannot identify the issue as a nonconformance.
 - What is the sampling plan, if required? How many test articles will be selected? How will test articles be selected?
 - What is the test article chain of custody? How are test articles uniquely identified? Where will test articles be securely stored while at the manufacturers? How will test article custody be secured during transport, if transported? Where will test articles be securely stored if tested at an outside facility? If you cannot ensure the chain of custody, then you cannot defend the results. The arguments that the chain of custody must eliminate are:
 - the article tested was not the article selected by EPA at the manufacturer's location.
 - the article tested was tampered with somewhere within the process when EPA took control of the article.
 - What is the methodology used to inform the manufacturers of the external visit? Develop templates so that you don't have to keep reinventing the wheel.
 - If upfront information is required from the manufacturer, how is it being gathered? Develop templates for consistency.

- Provide an agenda to the team and the manufacturer.
- Implementing
 - Follow the objectives defined.
 - Follow the checklists developed. No winging it -- this is where credibility is lost and the Agency's reputation is damaged. Be prepared before entering the manufacturer's site.
 - If testing is performed by LOD or a laboratory contracted by CISD, then a quality assurance project plan to cover the testing requirements and protocols is required.
- Reporting
 - How will the test results be captured/recorded? What is the report format?
 - How will issues be identified and recorded during the external visits?
 - Who provides feedback to the manufacturer if issues are identified?
 - Who prepares the draft and final reports? In what time frame?
 - What response is expected of the manufacturer, if issues are identified?
 - Who tracks the manufacturer's response and follows up?
 - What is the close out process? When is an audit over?
- Dispute process
 - What process is available to manufacturers if they feel that an issue was incorrectly identified?
 - Do the manufacturers know of the dispute process? They should be told of it.

Please let me know if you have any questions or comments regarding this note, I will be glad to add clarification. Also, if I need to schedule some time for reviews, let me know so that I can be available to support CISD's timing. Thank you,
Ruth

Ruth Schenk
OTAQ Quality Assurance
(734) 214-4017